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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,329	09/30/2003	Mark McCormick	700706.90181	5309

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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,329	MCCORMICK ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. GROSS	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 10/14/2008. Claims 1-16 are pending. Claims 1-6,14-16 are withdrawn. Claims 7-13 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/2008 has been entered.

Priority

The instant application has a filing date of 9/30/2003 and claims priority to provisional application 60415119 filed 9/30/2002.

Response to Arguments

In view of applicant's amendments to the claims and persuasive arguments, the present application is entitled to a priority date of 9/30/2002.

Withdrawn Rejection(s)

The rejection of claims 7-13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement concerning "new matter" is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 7-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 7-11,13 under 35 U.S.C. 102(b) as being anticipated by **Singh-Gasson et al** (1999 Nature Biotechnology 17:974-978) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 7-11,13 and 12 under 35 U.S.C. 103(a) as being unpatentable over **Singh-Gasson et al** (1999 Nature Biotechnology 17:974-978) in view of **Giegrich et al** (1998 Nucleosides & Nucleotides 17:1987-1996) is hereby withdrawn in view of applicant's amendments to the claims.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sheridan et al** (US Patent 6673315) in view of **Sundberg et al** (1995 JACS 117:12050-12057) and further in view of **Singh-Gasson et al** (1999 Nature Biotechnology 17:974-978 – PTO 892 4/14/2008).

The claimed subject per claim 7 is drawn to method for making a microarray having a plurality of subarrays surrounded by a visible or machine readable alignment mark in an interstitial region of the microarray, the method comprising the steps of:

a) selecting at least one probe set comprising probes of interest;
b) building the probe sets on a microarray to provide a plurality of subarrays,
wherein the probe sets are built with a maskless array synthesis instrument;
c) depositing a protected hapten
on the interstitial region of the microarray,
wherein the hapten is deposited by the same maskless array
synthesis instrument used to build the probe sets of step b);
d) deprotecting the hapten; and
e) attaching an illuminating compound to the hapten to form the alignment mark.

Claims 8-13 represent variations thereof.

Sheridan et al teach throughout the document and especially the abstract and figure 10, a method for manufacturing a biochip featuring fiducial markings for identifying the location of materials deposited on a substrate.

Figure 10 of Sheridan includes the step or arraying probes, which reads on “selecting at least one probe set comprising probes of interest," of claim 7a. Figures 6 and 7 of Sheridan et al illustrate “building probe sets on a microarray to provide a plurality of subarrays,” reading on claim 7b (in part) and “subarrays surrounded by a

visible or machine readable alignment mark in an interstitial region of the microarray, as set forth in claim 7c (in part) and the preamble of claim 7.

Fiducial (alignment) mark elements 216,304, etc. of Sheridan et al, such as illustrated in figure 3 appear to be quite flexibly deployable in the manner of present claim 13.

Sheridan et al do not teach: depositing a protected hapten of claim 7c; deprotecting said hapten of claim 7d; attaching an illuminating compound to the hapten to form an alignment mark of claim 7e; biotin haptens of claim 8; dye conjugated streptavidin reporter molecules, such as set forth in claims 9-10.

Sundberg et al teach, throughout the document and especially figure 3, deposition of "caged" biotin (elected species), for example, nitroveratryloxycarbonyl (Nvoc) biotin, a protected hapten, which reads on amended claim 7c and claim 8. Sundberg et al photolytically deprotect said biotin in figure 3, reading on amended claim 7d. Finally in figure 4, Sundberg et al mark the deprotected regions with fluorescein-streptavidin, dye conjugated streptavidin reporter molecule, reading on amended claim 7e and claims 9-10.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to utilize the caged biotin followed by marking with fluorescein-streptavidin of Sundberg et al with the method of manufacturing a biochip featuring fiducial markings according to Sheridan et al.

One of ordinary skill in the art would have been motivated to use the caged biotin followed by marking with fluorescein-streptavidin of Sundberg et al with the method of

manufacturing a biochip featuring fiducial markings according to Sheridan et al because (i) Sundberg et al explicitly suggest an embodiment using *fluorescent* fiducial marks and (ii) it is important to access individual sites with great accuracy, as noted by Sundberg et al in column 3, line 49 and column 1 lines 36-38, respectively.

One of ordinary skill in the art would have had a reasonable expectation of success in combining the caged biotin of Sundberg et al as a fiducial mark for the apparatus according to Sheridan et al because both references concern microarray fabrication, thus the material(s) of Sundberg et al lies well within the scope of technology according to Sheridan et al.

Sheridan et al in view of Sundberg et al do not teach: the maskless array synthesizer of claims 7b and 7c; photopatterning a group-bearing phosphoramidite wherein the hapen is deposited following photodeprotection by the mirrors of the maskless array synthesizer, as set forth in claim 11.

Singh-Gasson et al teach, throughout the document, and especially the title, and figure 1 synthesis of oligonucleotide microarrays using a maskless array synthesizer.

Singh-Gasson et al teach in figure 3, photodeprotection of (R,S)-1-(3,4-(methylenedioxy)-6-nitrophenyl)ethyl–hexaethlyeneglycol-cyanoethylphosphoramidite (MeNPOC-HEG-CEP), reading on claims 7b,c and 11.

One of ordinary skill in the art would have been motivated to use the maskless array synthesizer of Singh-Gasson et al for manufacturing a biochip featuring fiducial markings made from caged biotin and fluorescein-streptavidin per Sheridan et al in view

of Sundberg et al because maskless array synthesizers provide custom DNA chips at a lower cost and with a faster turnaround time, as noted by Singh-Gasson et al on p 974, first paragraph following the abstract.

One of ordinary skill in the art would have had a reasonable expectation of success in applying the maskless array synthesizer per Singh-Gasson et al toward manufacturing a biochip featuring fiducial markings made from caged biotin and fluorescein-streptavidin per Sheridan et al in view of Sundberg et al because all three references concern microarray fabrication and furthermore, Sundberg et al describe an alternative embodiment on p 12051 left column using MeNPOC caged biotin, the same photolytic protecting group as Singh-Gasson et al.

In conclusion, the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine

the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "phosphoramidite" in claim 12 is used by the claim to mean "2-(2 nitro phenyl) propoxy carbonyl (NPPOC)", while the accepted structure is typically $ROPOCH_2CH_2CN'N(iPr)_2$ where R is often a nucleoside. The term is indefinite because the specification does not clearly redefine the term.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1639